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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,050	06/15/2001	Edward M. Croze	BERLEX-88	5167
23599	7590	04/14/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/881,050	<b>Applicant(s)</b> CROZE ET AL.	
	<b>Examiner</b> Janet L. Andres	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 17 December 2003 is acknowledged. Claims 1-5 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The objection to the title is withdrawn in response to Applicant's amendment.
3. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as lacking antecedent basis for "the mammal in need thereof" is withdrawn in response to Applicant's amendments to claims 1 and 2 providing the appropriate language.

#### ***Claim Rejections Maintained***

4. The rejection of claims 1 and 2 under 35 U.S.C. 102(e) as anticipated by the '780 patent is maintained for reasons of record in the office action of 14 August 2003.

Applicant argues that the '780 patent distinguishes the polypeptide from interferon  $\beta$  and interferon  $\alpha$  and thus does not teach the instantly claimed interferon-beta2.

Applicant's arguments have been fully considered but have not been found to be persuasive. The instantly claimed polypeptide has the same sequence as the patented polypeptide. Its characteristics are determined by its sequence and are inherent to the molecule. Applicant's recognition of the interferon- $\beta$ -like characteristics of a compound already known does not render the compound itself novel. A protein is a protein; renaming it does not alter it.

5. The rejection of claims 3 and 4 under 35 U.S.C. 103(a) as unpatentable over the '780 patent in view of Polman et al. is maintained for reasons of record in the office action of 14 August 2003 and applied to new claim 5.

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Applicant argues that '780 patent teaches away from the claimed interferon beta2 by distinguishing "their interferon epsilon" from other type I interferons. Applicant further argues that Polman et al. does not teach that type I interferons use the same receptor, or that type I interferons in general would be useful for treating multiple sclerosis. Applicant argues that Cirelli et al. teaches that type I interferons do not all have the same affinity for the type I receptor and that others teach that clinical responses to the different type I interferons differ. Applicant particularly points to Pantich and the Austims Research Group as teaching that interferon  $\alpha$  does not affect the symptoms or progress of multiple sclerosis.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, "their interferon epsilon" is Applicant's interferon beta2. The name does not change the polypeptide. Applicant is correct that the '780 patent does not teach that this polypeptide is an interferon  $\beta$ ; as stated previously, the '780 patent teaches that it is a type I interferon. Polman does in fact teach that type I interferons use the same receptor (see p. 561, column 1), although Polman does not mention the existence of type I interferons other than alpha and beta. The '780 patent also teaches that type I interferons use the same receptor (column 2, lines 55-67, and column 3, lines 1-6) and teaches that the protein of SEQ ID NO: 1 is a type I interferon. The '780 patent as well as the references cited by Applicant teach differences in biological effects among type I interferons. However, type I interferons are similar in their applications and more recent work than that cited by Applicant, which nonetheless predates Applicant's application, teaches that type I interferons other than interferon  $\beta$  have been shown to be useful for treatment of multiple sclerosis. Brod et al. (Multiple Sclerosis, 1997 vol. 3 (1) 1-7) teaches that interferon  $\alpha$  is in fact useful to treat multiple sclerosis. See discussion, pp. 5-6.

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Durelli et al. (Neurology, 1998, vol. 47, pp. 123-129) also teaches treatment of multiple sclerosis with interferon  $\alpha$  and provides evidence of improvement of symptoms by interferon  $\alpha$ . See discussion, pp. 127-188. U.S. patent 6,372,206, filed 1996, teaches the interferon  $\alpha$ -like type I interferon interferon  $\tau$  and teaches that it can be used to treat multiple sclerosis (column 4, lines 41-47, column 9, lines 50-59). The '206 patent shows that interferon  $\tau$  can be successfully used in a mouse EAE model, an accepted model for multiple sclerosis (column 9, lines 29-36). Similar results are shown by Khan et al. (Multiple Sclerosis, 1998, vol. 4 (2) 63-9); see discussion, pp. 67-68. Thus the art generally teaches that not only interferon  $\beta$ , but also other type I interferons can be used to treat multiple sclerosis. Applicant's identification of interferon- $\beta$  like characteristics is not required to provide motivation to use the protein to treat multiple sclerosis; such motivation is already present in the prior art, taken as a whole, which shows that type I interferons are useful to treat multiple sclerosis. The teaching of an early failed experiment clearly did not suffice to teach away from this use; subsequent workers pursued it with success. Thus, given the state of the art at the time, it would have been obvious to one of ordinary skill to combine the teachings of the '780 patent with those of Polman et al. to use the interferon of the "780 patent to treat multiple sclerosis. One of ordinary skill would have been motivated to do so because both Polman et al. and the relevant art at the time the invention was made teach that such a use would be successful.

NO CLAIM IS ALLOWED.

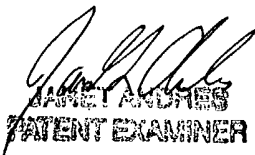
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
6 April 2004



**JANET ANDRES**  
**PATENT EXAMINER**